

REMARKS

Claims 27 and 49 have been amended. Claims 27, 49, 64, 67, 68, 71-74, 76, 77, 79, 81-86, 89-91, 94, 96, 97, 102, 104, 105, 110, 111, 114, 115, 119, 121-123, 126, 128, 129, 131-135, 138, 139, 144-168, 170, 172, and 174-178 are pending in the instant application. Support for the amendments to the claims can be found in the specification at, for example, page 5, lines 7-39; page 5, line 45 to page 6, line 3; page 21, lines 28-33; and page 22, line 37 to page 23, line 4 and page 23, lines 16-21. The objections and rejections set forth in the Office Action have been overcome by amendment or are traversed by argument below.

1. Rejection of claims 27, 49, 64, 67, 71-74, 76, 77, 79, 81, 83-86, 89-91, 94, 96, 97, 102, 104, 105, 110, 114, 115, 119, 121-123, 126, 128, 129, 131-135, 138, 139, 144-167, 170, 172, and 174-178 under 35 U.S.C. § 102

The Office Action maintains a rejection of claims 27, 49, 64, 67, 71-74, 76, 77, 79, 81, 83-86, 89-91, 94, 96, 97, 102, 104, 105, 110, 114, 115, 119, 121-123, 126, 128, 129, 131-135, 138, 139, 144-167, 170, 172, and 174-178 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,695,953 (the '953 patent), which the Action asserts has an effective priority date of September 12, 1988. The Action states that while Applicants' arguments in the response to the Office Action mailed July 29, 2005 are persuasive that the purified protein of the '953 patent was a mixture of two TNF-BP's of different lengths, the pending claims encompass nucleic acid molecules encoding more than one form of soluble TNF-BP, including the claimed nucleic acid molecules of the '953 patent. The Action also states that "[e]ven though [the '953 patent] did not disclose a nucleic acid molecule that would encode a TNF-BP of SEQ ID NO: 4 of the instant application, the Examiner is barred from allowing claims to the nucleic acid in the instant application." Finally, the Action suggests that if the claims were amended to distinguish over the claimed nucleic acid molecules of the '953 patent, the rejection would be withdrawn.

Applicants have amended claim 27 to recite an isolated nucleic acid molecule comprising the nucleotide sequence as set forth in SEQ ID NO: 3, wherein the isolated nucleic acid molecule does not further comprise residues 88-120 or residues 604-633 of the nucleotide sequence of SEQ ID NO: 1. Applicants have also amended claim 49 to recite an isolated nucleic acid molecule encoding a polypeptide having the ability to bind TNF, wherein said polypeptide comprises the amino acid sequence as set forth in SEQ ID NO: 4, and wherein said polypeptide does not comprise residues 30-

40 or 202-211 of the amino acid sequence set forth in SEQ ID NO: 2. Support for the amendments to claims 27 and 49 can be found in the instant specification, which discloses (a) the amino acid sequences of a TNF receptor polypeptide (*see, e.g.*, page 5, lines 7-39) and a 161 amino acid portion of this sequence having the ability to bind TNF (*see, e.g.*, page 5, line 45 to page 6, line 3); (b) that the first 29 amino acid residues of the TNF receptor polypeptide set forth in SEQ ID NO: 2 constitute the signal peptide (*see, e.g.*, page 21, lines 28-33), and (c) that amino acid residues 30-40 and 202-211 of the amino acid sequence set forth in SEQ ID NO: 2 are proteolytically cleaved from the TNF receptor to form the TNF binding protein (*see, e.g.*, page 22, line 37 to page 23, line 4 and page 23, lines 16-21).

As the Examiner acknowledges in the instant Action, the '953 patent does not disclose a nucleic acid molecule that encodes the TNF-BP of SEQ ID NO: 4. While amended claims 27 and 49 encompass a nucleic acid molecule encoding SEQ ID NO: 4, none of the other members of the genus of nucleic acid molecules defined by claims 27 and 49 encodes "a naturally occurring" soluble TNF inhibitory protein as required by the claims of the '953 patent, since none of the other members of this genus comprise residues 30-40 and 202-211 of the amino acid sequence set forth in SEQ ID NO: 2. Because the '953 patent does not anticipate the nucleic acid molecules encompassed by the pending claims, Applicants respectfully request that the rejection of claims 27, 49, 64, 67, 71-74, 76, 77, 79, 81, 83-86, 89-91, 94, 96, 97, 102, 104, 105, 110, 114, 115, 119, 121-123, 126, 128, 129, 131-135, 138, 139, 144-167, 170, 172, and 174-178 on 35 U.S.C. § 102 grounds be withdrawn.

Applicants note that claims 27 and 49 have been amended in an effort to expedite prosecution of the pending claims to allowance, and not because Applicants believe that the claims of the '953 patent satisfy the requirements for patentability or that the '953 patent is entitled to an earlier priority date than the instant application. As Applicants stated in their response to the Office Action mailed July 29, 2005, the '953 patent provides only a *partial, incomplete* amino acid sequence of a TNF inhibitory protein – and *no nucleotide sequence whatsoever* (*see* col. 4, ln. 27- 31; col. 10, ln. 43-46; and col. 12, ln. 32-37). Because the '953 patent does not disclose *any* information about the nucleotide sequence of TNF binding protein (TNF-BP) – and discloses *only* fourteen of the first sixteen amino acid residues of a TNF-BP, it is clear that the '953 did not place the nucleotide sequence of TNF-BP into the public's possession, and therefore, did not provide an adequate written description of the nucleotide sequence of TNF-BP. In addition, because a skilled artisan could not have combined the disclosure of the '953 patent with her own knowledge to make the nucleotide

sequence of TNF-BP, the '953 patent also lacks an enabling disclosure with respect the nucleotide sequence of TNF-BP. Applicants, therefore, reserve the right to re-introduce previously presented claims 27 and 49 (or other claims supported by the instant specification) if Applicants decide to pursue the course of action set forth in 37 C.F.R. § 1.607.

2. Rejections of claims 147 and 164 under 35 U.S.C. § 103(a)

The Office Action maintains a rejection of claims 147 and 164 under 35 U.S.C. § 103(a), as being unpatentable over the '953 patent, in view of U.S. Patent No. 4,847,325 (the '325 patent). The Office Action mailed July 29, 2005 states that the '325 patent discloses that proteins can be conjugated to a water-soluble polymer, resulting in a biologically active protein having increased circulating half-life in mammals as compared to the unconjugated protein. The Action asserts, therefore, that it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to chemically derivatize the TNF-BP disclosed in the '953 patent with a compound such as PEG, since the '325 patent discloses that the half-life of the protein would be increased *in vivo*.

As described in section 1 above, the '953 patent does not anticipate the nucleic acid molecules encompassed by the pending claims. Because the disclosure of the '325 patent does not compensate for the shortcomings in the '953 patent, Applicants respectfully request that the rejection of claims 147 and 164 under 35 U.S.C. § 103(a) be withdrawn

CONCLUSIONS

Applicants respectfully contend that all conditions of patentability are met in the pending claims as amended. Allowance of the claims is thereby respectfully solicited.

If Examiner O'Hara believes it to be helpful, she is invited to contact the undersigned representative by telephone at 312-913-0001.

Respectfully submitted,
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Dated: December 26, 2006

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